U.S. Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DMID-08-04
"Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases"

OMB Control Number 0990-0115

1. **OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.** http://www.fedbizopps.gov/

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:** May 14, 2007	5. **Small Bus. Set-Aside:** [X]Yes [ ] No
January 2, 2007	**Time:** 3:00 P.M., EST	**8(a) Set-Aside:** [ ]Yes [X] No
		NAICS: 541710; 500 employees
		(See Part IV, Section L.)

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[X] No	[X] Only 1 Award	[ ] No
[ ] Yes (See Part IV, Section L.)	[ ] Multiple Awards	[X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)

9. **Issued By:**	10. [x] **NIAID reserves the right to make awards without discussion.**	
Teresa Baughman Contracting Officer, MIDRCB-B Office of Acquisitions, DEA, NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[X] No** **[ ] Yes** (See Part IV, Section L.)	12. **Period of Performance:** 7 Years: March 3, 2008 through March 2, 2015

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Debby Baca	**Name:** Teresa (Terry) Baughman	Director, OA
Phone: 301-443-4490	**Phone:** 301-451-3690	Address (see Block 9.)
Fax: 301-402-0972	**Fax:** 301-402-0972	
E-Mail: dbaca@niaid.nih.gov	**E-Mail:** baughmat@niaid.nih.gov	

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Debby Baca, Contract Specialist Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Debby Baca, Contract Specialist Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

13. DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR *(i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the offeror's proposal and requiring Contracting Officer Prior Approval)* WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract provides for the establishment and management of a Statistical and Data Coordinating Center (SDCC) to support the Division of Microbiology and Infectious Diseases' (DMID) extramural clinical research programs through the provision of: statistical design and analysis expertise; computerized systems for the collection, storage, management, reporting and quality control of study data; assistance in the preparation of study-related materials and instructions; a system for the tracking of clinical specimens; training of clinical site staff and assessment of clinical site capabilities for data collection and management; and a data repository for completed DMID-sponsored clinical studies.

The Contractor shall support a variety of clinical research projects funded under grant and contract mechanisms, including studies of potential agents of bioterrorism. Studies to be supported shall be conducted within and outside of the United States and, when necessary, shall include clinical research focused on urgent public health needs and opportunities, particularly with respect to emerging and re-emerging infectious diseases.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $_____.

b. The fixed fee for this contract is $_____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $_____.

d. Total funds currently available for payment and allotted to this contract are $_____, of which $_____ represents the estimated costs, and of which $_____ represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through _____.

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 25, 2006, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

In addition to the required reports set forth elsewhere in the Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. Please refer to the "Reporting Requirements and Deliverables" in SECTION J - List of Attachments.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted to the Contracting Officer on the completion date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the completion date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Division of Extramural Activities
Office of Acquisitions
6700-B RockledgeDrive, Room 3241, MSC 7612
Bethesda, Maryland 20892 - 7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer identified in Article G.1., is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed by the Project Officer at DMID, NIAID, NIH.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items specified in the delivery schedule described in SECTION C of this contract.

The items described in SECTION C, ARTICLE C.2. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified in SECTION C, ARTICLE C.2. and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract.

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

The personnel specified in this contract are considered to be essential to the work to be performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this article. The contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

The following individuals are considered to be essential to the work being performed hereunder:

NAME	TITLE
[To be specified prior to award]	

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(1) Invoices/financing requests shall be submitted as follows:

(a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN266200811000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-AI -81234.)

(b) An original and two copies to the following designated billing office:

Contracting Officer
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Diseases, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-0612.

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. __ - __ and the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

c. The following is a listing of expenditure categories that may be required to be reported on your invoice:

Expenditure Category

(1) Direct Labor

(2) Other Professional Personnel

(3) Personnel - Other

(4) Fringe Benefits

(5) Accountable Personal Property

(6) Materials/Supplies

(7) Travel

(8) Consultant Costs

(9) Premium Pay

(10) Subcontract Costs

(11) Other Direct Costs

(12) Indirect Costs

(13) G&A Expense

(14) Total Cost

(15) Fee

(16) Total Cost Plus Fixed Fee

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 Executive Boulevard, MSC 7540
Bethesda, MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted at least once during the performance of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for: (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

   Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.3. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.4. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document may be accessed on the Internet at http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm.

ARTICLE H.5. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as “indirect costs” or “facilities and administrative

(F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. **Public Law and Section No.*** **Fiscal Year*** **Dollar Amount of Salary Limitation***

[*Applicable information to be included at award]

c. Payment of direct salaries is limited to the Executive Level rate which was in effect on the date(s) the expense was incurred.

ARTICLE H.6. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to: (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

a. Information Type

[ ] Administrative, Management and Support Information:
[ ] Mission Based Information:

b. Security Categories and Levels

Confidentiality	Level:	**[ ]** Low	**[ ]** Moderate	**[ ]** High
Integrity	Level:	**[ ]** Low	**[ ]** Moderate	**[ ]** High
Availability	Level:	**[ ]** Low	**[ ]** Moderate	**[ ]** High
Overall	**Level:**	**[ ] Low**	**[ ] Moderate**	**[ ] High**

c. Position Sensitivity Designations

(1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

[ ] **Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI)**. Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[ ] **Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI)**. Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[ ] **Level 1: Non Sensitive (Requires Suitability Determination with an NACI)**. Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

(2) The contractor shall submit a roster, by name, position and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ais.nci.nih.gov/forms/Suitability-roster.xls.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(3) Contractor/subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/subcontractor employees may begin work under the contract after he contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor/subcontractor employee to work under the contract.

d. Information Security Training

The contractor shall ensure that each contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: http://irtsectraining.nih.gov/ prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The contractor shall maintain a listing by name and title of each contractor/subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by contractor/subcontractor staff shall be included on this listing. [The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.]

Contractor/subcontractor staff shall complete the following additional training prior to performing any work under this contract:

e. Rules of Behavior

The contractor/subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: http://irm.cit.nih.gov/security/nihitrob.html.

f. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

-18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
-18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
-Public Law 96-511 (Paperwork Reduction Act)

(2) Contractor-Employee Non-Disclosure Agreements

Each contractor/subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

h. NIST SP 800-26 Self-Assessment Questionnaire

The contractor shall annually update and re-submit its Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form (http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf - See Appendix B for format).

Subcontracts: The contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the contractor's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the contractor's/subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer the 30th of the month following each anniversary date of the contract.

i. Information System Security Plan

The contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The contractor shall include similar information for any subcontractor performing under the SOW with the contractor whenever the submission of an ISSP is required.

ARTICLE H.7. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

The contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The contractor shall provide the contracting officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, a copy of the storage facility(s) certificate of compliance with the NARA requirements shall be included with this information.

Sixty (60) days prior to contract end date, the contractor shall submit to the Project Officer and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the completion date of the contract.

ARTICLE H.8. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/.

ARTICLE H.9. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. N01-AI-xxxxx.

ARTICLE H.10. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.11 . REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.12. ANTI-LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.13. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

The complete listing of these clauses may be accessed at:
http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19, Notification Of Ownership Changes** (October 1997), are deleted in their entirety.

Alternate IV (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.

FAR Clauses **52.219-9, Small Business Subcontracting Plan** (September 2006), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.

FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. ***[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]***

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

(2) FAR Clause **52.219-6, Notice of Total Small Business Set-Aside** (June 2003).

(3) FAR Clause **52.219-14, Limitations on Subcontracting** (December 1996).

(4) FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

(5) FAR Clause **52.224-2, Privacy Act** (April 1984).

(6) **Alternate II** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

(7) **Alternate V** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

(8) FAR Clause **52.227-15, Representation of Limited Rights in Data and Restricted Computer Software** (June 1987).

(9) FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

(10) FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June2003).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

(1) HHSAR Clause **352.224-70, Confidentiality of Information** (March 2005).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) Definition. As used in this clause--

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are provided as either attachments to this RFP or can be accessed through the provided web links.

ATTACHMENTS TO THIS SOLICITATION : (The following documents are incorporated into this RFP)

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Reporting Requirements and Deliverables	See Attachment Sections at the end of this RFP
Attachment 5:	Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 6:	Additional Business Proposal Instructions and Uniform Budget Assumptions	See Attachment Section at the end of this RFP
Attachment 7:	DMID-Funded Clinical Research Support Services Contracts	See Attachment Section at the end of this RFP
Attachment 8:	DMID Clinical Research Contracts	See Attachment Section at the end of this RFP

DOCUMENTS TO BE ATTACHED TO THE TECHNICAL PROPOSAL : (The following documents must be completed, where applicable, and submitted with the Technical Proposal. They can be located at the electronic Web links provided below and are, therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

DOCUMENTS TO BE ATTACHED TO THE BUSINESS PROPOSAL : (The following attachments must be completed, where applicable, and submitted with the Business Proposal. They can be located at the electronic Web links provided below and are, therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL DOCUMENTS: (The following Documents and Reports will become attachments to any contract resulting from this RFP and will be required during contract performance. They can be located at the electronic Web links provided below and are, therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Privacy Act System of Records *System of Records No. 09-25-0200 is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm
Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Government Property Schedule	http://www.niaid.nih.gov/contract/forms/form9.pdf
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2004)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--
- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want

used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted,

the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

b. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500 employees.

c. **TYPE OF CONTRACT AND NUMBER OF AWARDS**

It is anticipated that one award will be made from this solicitation and that the award will be made on/about March 3, 2008.

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost reimbursement, completion type contract, with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to require approximately 40.75 total FTEs. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

g. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

i. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. **SERVICE OF PROTEST** (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Diseases, NIH, DHHS
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

k. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments. **(See also, Additional Technical Proposal Instructions, Attachment 5)**.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments. **(See also, Additional Business Proposal Instructions and Uniform Budget Assumptions, Attachment 6)**.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD.)

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be

evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(10) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(11) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution

identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(12) **Past Performance Information**

a) Offerors shall submit the following information as part of their **business** proposal.

A list of the last five (5) contracts completed during the past three (3) years and the last three (3) contracts awarded that are similar in nature to the solicitation work scope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract over $550,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(13) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(14) **Prohibition on Contractor Involvement with Terrorist Activities**

The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

(15) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).

b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

NOTE: Offerors are also advised to also refer to the information included in Attachment 5, "Additional Technical Proposal Instructions" when preparing their Technical Proposal.

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education:** The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

b) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated

as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in SECTION M - Evaluation Factors for Award of this solicitation.

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "INFORMATION SECURITY."

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

(a) Information Type

[X] Administrative, Management and Support Information:
[ ] Mission Based Information:

(b) Security Categories and Levels

Confidentiality	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Integrity	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Availability	Level:	**[ ]** Low	**[X]** Moderate	**[ ]** High
Overall	**Level:**	**[X] Low**	**[ ] Moderate**	**[ ] High**

(c) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor (including subcontractor) employee that the successful offeror proposes for work under the contract. For proposal preparation purposes, the following designations apply:

[ ] Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[ ] Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ais.nci.nih.gov/forms/Suitability-roster.xls

Upon receipt of the Government's notification of applicable Suitability Investigations required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(d) Information Security Training

HHS policy requires contractors/subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: [insert link for course] prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements (http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf). This document provides information about information security training that may be useful to potential offerors.

(e) Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

(f) NIST SP 800-26 Self-Assessment Questionnaire

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form at: (http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf, See Appendix B for submission format.) NIST 800-26 assesses information security assurance of the offeror's internal systems security. This assessment is based on the Federal IT Security Assessment Framework and Draft NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems, at: (http://www.csrc.nist.gov/publications/drafts/800-53-rev1-clean-sz.pdf).

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

(g) Draft Information System Security Plan

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800-18, Guide to Developing Security Plans for Federal Information Systems (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

(h) References

(1) Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/

The following NIST publications may be found at the following site: http://csrc.nist.gov/publications/ *[Note: The search tool on the left side of this page provides easy access to the documents.]*

(4) NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
(5) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
(6) NIST SP 800-26, Revision 1, Computer Security
(7) NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems

(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and
Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
(9) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
(10) FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
(11) FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

c. BUSINESS PROPOSAL INSTRUCTIONS

NOTE: Offerors are also advised to also refer to the information included in Attachment 6, "Additional Business Proposal Instructions and Uniform Budget Assumptions" when preparing their Business Proposal.

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

   Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

   Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

   Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

(4) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) **Salary Rate Limitation in Fiscal Year 2007**

Offerors are advised that pursuant to P.L. **, no NIH Fiscal Year 2007 (October 1, 2006 - September 30, 2007) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. ** applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. ** states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/06tables/indexSES.asp

***Note to offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2007 Executive Level I Salary rates.*

***Pending Passage of Legislation.*

(6) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(7) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(8) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

c) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38**, (May 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract

modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

f) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(9) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(10) **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(11) **Representations and Certifications - SECTION K**

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

(12) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

(13) **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performend in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

(1) **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance, and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

(2) **TECHNICAL EVALUATION CRITERIA**

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO BOTH SECTION L and ATTACHMENT 5, "ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS" OF THIS SOLICITATION FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF THE TECHNICAL PROPOSAL.

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. Subcriteria, if not weighted, should be considered to be of equal importance.

CRITERIA	**WEIGHT**
CRITERION 1: TECHNICAL PLAN/APPROACH	**40**

1. Data Collection, Management and Quality Control: Ability to collect, manage and control the quality of clinical and laboratory data as evidenced by the soundness, appropriateness, adequacy and feasibility of the proposed computer-based system(s) and plans and procedures for data collection and data entry system(s), logic checks and data integrity verification, halting rules requirements, reporting and distribution of data and reports, locking of data, compliance with regulatory and international guidance, computer based randomization, security of data and data storage.

2. Study-Related Materials: Ability to design, manage, update and ensure secure access to clinical study materials and data in real time as evidenced by the soundness, appropriateness, adequacy and feasibility of the plans and procedures for creating CRFs, MOOs, data management plans, and plans and procedures for distributing study-related materials, including past example(s) and experience.

3. Clinical Study Websites: Ability to design, manage, update and ensure secure access to Clinical Study Website(s) as evidenced by the soundness, appropriateness, adequacy and feasibility of the plans and procedures for establishing the necessary web-sites, including plans for the number and content of each web-site, security procedures, real-time secure access to study materials, including past example(s) and experience.

4. Statistical Design and Analysis: Ability to carry out statistical design and analysis functions as evidenced by the soundness, appropriateness, adequacy and feasibility of the scientific, technical and operational plans for the statistical design of clinical trials in infectious diseases, the development of protocol-specific data analysis plans, and the preparation of interim and final study analyses for safety monitoring and for compliance with regulatory requirements, including pre- and post-regulatory submissions.

5. Electronic Specimen Tracking System: Ability to design and manage an electronic specimen tracking system as evidenced by the soundness, appropriateness, adequacy and feasibility of the scientific, technical and operational plans for the receipt, storage and maintenance of specimen data.

6. Study Communication, Collaboration and Reporting: Ability to coordinate with DMID CTM Contractor and Clinical and Regulatory Affairs Support Contractor as evidenced by the soundness, appropriateness, adequacy and feasibility of the collaboration and communication plans.

7. Clinical Site Training, Assessment and Technical Assistance: Ability to provide clinical sites training, assessment and technical assistance as evidenced by the soundness, appropriateness, adequacy and feasibility of the proposed training modules, plans to provide full time technical consultation, plans and procedures for conduct of study initiation meeting, plans and procedures for site assessment, the ability to provide webcasts and teleconference including past examples and the proposed plans and activities for establishing or modifying SDCC computerize system, including the on-site assessment of such systems.

CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL **20**

1. Principal Investigator: Appropriateness and adequacy of the education, training, experience, expertise and effort of the proposed Principal Investigator with respect to the following:

    a. The design and analysis of clinical trials, clinical studies and other evaluations and analyses for testing the safety and efficacy of vaccine and therapeutic candidates for infectious diseases.

    b. The management and oversight of a clinical trials data coordinating center, including support for multi-site trials and studies, with respect to ensuring adherence to Federal regulations, Good Clinical Practice, and protocol-specific requirements for the data collection. This includes the development and implementation of standard operating procedures and plans for quality assurance/quality control; the identification of performance problems and deficiencies; and the implementation of remedial actions to address performance problems and deficiencies.

    c. Collaborating with clinical investigators, industry and clinical research support services contractors with respect to study design, statistical analysis, preparation of and reporting on study data for Investigational New Drug (IND) applications, data management and quality control, and clinical site monitoring.

2. Other Scientific and Technical Personnel: Appropriateness and adequacy of the education, training, experience, expertise and level of effort of other proposed scientific and technical personnel of the Offeror and all proposed subcontractors, including the adequacy of the proposed mix of staff, expertise, experience, and training, to carry out contract requirements with respect to the following:

    a. the design of clinical trials and clinical studies of candidate vaccines and therapeutics for infectious diseases in accordance with Federal regulatory requirements, protocol-specific requirements, and Good Clinical Practice;

b. the ability and knowledge to perform clinical site assessments and provide technical assistance to study sites;
c. the ability and knowledge to provide clinical site training on the proposed data systems;
d. the design of data analysis plans and the preparation of interim and final analysis of clinical and laboratory data; and
e. Information Technology support.

CRITERION 3: FACILITIES, EQUIPMENT AND OTHER RESOURCES **15**

The availability and suitability of the facilities, equipment and other resources of the Offeror and all proposed subcontractors for the conduct of clinical trials data collection, management and quality control, data analysis and reporting in accordance with Federal regulatory requirements and guidelines, including Good Clinical Practice, NIH, NIAID and DMID policies and procedures, and the scope and requirements of the contract. This includes:

1. Secured computer system(s);
2. Backup computer system;
3. Live support 24-hours per day/7 days per week; and
4. Other facilities and equipment, including: all computers, hardware and software, computer equipment and servers; space for staff and equipment; controlled access areas for secure storage of study data and confidential study information; and web-cast and video capability for training purposes that can be uploaded to the internet.

CRITERION 4: OVERALL PROJECT MANAGEMENT **15**

1. Adequacy of the plans for the staffing, organization, distribution of responsibilities, leadership and lines of authority for carrying out contract requirements;
2. Suitability of systems proposed for tracking contract activities and monitoring progress, time lines and budgets;
3. Suitability of plan for how the Principal Investigator will communicate with the Project Officer and the Contracting Officer, as well as established lines of communication among all performance sites and activities; and the DMID-funded Clinical Research and Clinical Research Support Services contracts; and
4. Suitability of the plan for how the Contractor will safeguard data and materials.

CRITERION 5: INITIAL TRANSITION **10**

Ability to plan and implement a secure, orderly and efficient transition of clinical and laboratory data, study-related materials, and other contract-generated resources as evidenced by the soundness, appropriateness, adequacy and feasibility of the plans and procedures for the initial transition addressing: transition timelines; ability to affect a seamless transition for all studies that are currently enrolling, producing final study reports and other required regulatory reports for completely enrolled studies; and access to archived data.

TOTAL POSSIBLE POINTS **100**

(3) **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechnaical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgement by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments

PACKAGING AND DELIVERY OF THE PROPOSAL

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

SUBMISSION OF PROPOSALS BY FACSIMILE OR E-MAIL IS **NOT** ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"**RFP NO. NIH-NIAID-DMID-08-04**
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Debby Baca Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Debby Baca Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

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C. NUMBER OF COPIES:

TOTAL PAGE COUNT DOES NOT INCLUDE: Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section.

PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.

FORMATTING AND LAYOUT:
Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information. *Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.*

2. It is requested that the Technical Proposal be submitted as one document.

   Note: if multiple files are submitted for the either proposal, please include the name of the section in the file name.

   EXAMPLE: XYX Company-08-04-Technical-Approach-3-6-06

3. CDs should be named using the following format:

   Technical Proposal: ***Company name-RFP number-technical-date***
   Business Proposal: ***Company name-RFP number-business-date***

THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Six (6) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	**Not to Exceed 200 pages (inclusive of all Attachments and Appendices)**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-08-04
RFP Title: Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **March 31, 2007**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
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Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
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(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
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6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Attn: Debby Baca
RFP-NIH-NIAID-DMID-08-04
FAX# (301) 402-0972
Email: dbaca@niaid.nih.gov

STATEMENT OF WORK

Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases RFP NIH-NIAID-DMID-08-04

BACKGROUND and INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents other than HIV. This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics which are funded through a variety of research grants and contracts.

The evaluation of new and improved vaccine and therapeutic candidates in clinical trials and clinical studies is an essential element of the efforts of DMID. Through an extensive network of grant and contract research programs, DMID supports a broad range of clinical research, including single-site and multi-center Phase 1, Phase 2, Phase 3, and Phase 4 clinical trials of bacterial, viral and parasitic vaccines, therapeutics, and other biologics and drugs as preventive and therapeutic measures against infectious diseases in people of all ages and risk categories. Support is also provided for a variety of other studies, including: targeted surveillance for pathogens of interest in study populations; evaluations of novel investigational product delivery systems; and reevaluation of current vaccine formulations, schedules and modes of delivery. Clinical trials and clinical studies are also supported to evaluate the safety and efficacy of vaccines and therapeutics against potential agents of bioterrorism, including NIAID priority biodefense pathogens (http://www3.niaid.nih.gov/Biodefense/bandc_priority.htm), and to meet critical public health needs and opportunities for emerging and re-emerging infectious diseases, such as Severe Acute Respiratory Syndrome (SARS) and avian influenza.

This contract provides for the establishment and management of a Statistical and Data Coordinating Center (SDCC) to support DMID's extramural clinical research programs through the provision of: statistical design and analysis expertise; computerized systems for the collection, storage, management, reporting and quality control of study data; assistance in the preparation of study-related materials and instructions; a system for the tracking of clinical specimens; training of clinical site staff and assessment of clinical site capabilities for data collection and management; and a data repository for completed DMID-sponsored clinical studies.

SCOPE

The Contractor shall serve as the SDCC for clinical research programs supported by DMID with responsibility for carrying out the following functions:

1. *Data collection, management and quality control* – the provision of state-of-the-art computer-based systems for the collection, storage, management, security and quality control of all study data, including systems of subject enrollment and randomization.
2. *Study-related materials* – the preparation of materials for the implementation of clinical trials and clinical studies, including manuals of operation (MOOs), electronic case report forms (CRFs), source documents and tracking logs.

3. *Website development and access* – the development and maintenance of protocol websites to share information and study materials with DMID and participating sites, and to provide real-time study information, overall and site-specific, including accrual, demographics, adverse events and protocol deviations.
4. *Study communication, collaboration and reporting* – the sharing of information with DMID and DMID contractors to implement study procedures and to evaluate study processes.
5. *Statistical design and analysis* – the provision of statistical leadership, consultation and design expertise for the development, implementation and analysis of clinical trials and clinical studies in infectious diseases other than HIV, including the preparation of interim and final statistical analyses.
6. *Clinical site training, assessment and technical assistance* – the development of training materials and the conduct of training for clinical site staff and the assessment of clinical site capability for data collection, management and quality control.
7. *Electronic specimen tracking system* – the development and management of an electronic system for tracking all clinical specimens.
8. *Data storage* – the receipt and storage of data from completed clinical trials and clinical studies.

The scope of clinical research programs to be supported by the Contractor includes:

- **Scope of Infectious Diseases** - the evaluation of candidate vaccines, therapeutics, and other biologics and drugs, as well as other types of evaluations and analyses, for viral (other than HIV), bacterial, parasitic and fungal pathogens, including NIAID priority biodefense pathogens.

- **Scope of Candidate Vaccines and Therapeutics** - the evaluation of live, attenuated, killed, vectored, DNA or combination vaccines, adjuvants, therapeutic agents and biologics including novel immunomodulatory agents. In addition, new approaches to vaccine, drug and therapeutic delivery systems; dose finding; and change in regimen and schedule shall also be evaluated.

- **Scope of Clinical Research** – Phase 1 and 2 clinical trials to evaluate candidate vaccines and therapeutics to determine safety, immunogenicity, reactogenicity, optimal dose and schedule, infectivity, degree of virulence or attenuation, transmissibility, genetic stability, and pharmacogenomic studies. Selected Phase 3 and 4 clinical trials for safety and efficacy.

- **Study Populations** – general populations, including pediatric, adult and elderly subjects, as well as additional populations such as women of reproductive age, pregnant women, immunocompromised populations, non-U.S. populations, and populations with underlying medical conditions.

The Contractor shall support a variety of clinical research projects funded under grant and contract mechanisms, including studies of potential agents of bioterrorism. Studies to be supported shall be conducted within and outside of the U.S. and, when appropriate/necessary, shall include clinical research focused on urgent public health needs and opportunities, particularly with respect to emerging and re-emerging infectious diseases.

Current DMID-funded clinical research programs to be supported by the SDCC are described in the Attachment 7 entitled “DMID-Funded Clinical Research Contracts.”

TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the following functions:

1. **Data Collection, Management and Quality Control**

   a. The Contractor shall be responsible for operating and maintaining state-of-the-art computer-based systems at a central facility and for implementing related system procedures for the collection, management, storage, and quality control of all clinical and laboratory research data and for the management and reporting of data and other information for clinical trials and clinical studies supported under the contract. The system(s) shall provide for the use of remote data entry via the web for the majority of studies supported. The Contractor shall make other accommodations for data entry by a small number of study sites with questionable computer capability and/or internet connection. These systems must be in place within 90 calendar days from the effective date of the contract.

   b. Computer-based System(s) for Data Collection, Storage, Tracking and Retrieval shall provide the following features and capabilities:

      1) Receiving, entering, verifying, labeling, processing, editing (including within and across form validity, logic, and consistency checks), updating, correcting, freezing, locking, storing, securing, tracking, and retrieving all clinical and laboratory data at a central data management facility.

      2) Compliance with all current Federal regulations (§21 CFR 11 and/or similar statutes, http://www.fda.gov/cber/guidelines.htm) and meet current globally-accepted standards, including International Conference on Harmonization (ICH) E-2, Clinical Safety Data Management and ICH M-5, Data Elements and Standards for Drug Dictionaries (http://www.ich.org/cache/compo/475-272-1.html and http://www.ich.org/cache/compo/2196-272-1.html, respectively).

      3) Central computerized registration and randomization of the majority of subjects on DMID protocols, and non-computerized methods as needed on a limited basis for selected study sites.

      4) Computerized study forms and systems for remote data entry and transmission, generally via the internet, of subject data from study sites and laboratories to the central data management facility; non-computerized methods when necessary, for example paper CRF.

      5) Real-time electronic notification of appropriate DMID personnel, i.e. Project Officer and Medical Officers designated by the Project Officer, in the event data trigger halting rules.

      6) Compatibility with the systems being used by DMID and provision of all related software.

      7) Evaluate quality assurance data generated in connection with the clinical trials.

      8) For high priority studies, daily e-mail notification to relevant DMID staff designated by the Project Officer and participating study sites regarding accrual and study status.

9) Security against anticipated risks, including loss of confidentiality of subject electronic records and data summaries, and catastrophic loss of study data or important software, including an off-site secured storage facility for system back-ups.

   a) References for system security information and guidance are located in Section H of the contract at the end of the Article entitled "Information Security."

   b) A System's Security Plan (SSP), which minimally shall include the Risk Analysis (RA) and the Continuity of Operations Plan (COOP -- also known as the Contingency Plan).

   c) The preparation and submission of an annual Information System Security Plan (ISSP), following the instructions in the HHS SecureOne Policy http://intranet.hhs.gov/infosec/about.html, for review and approval by the Project Officer and the NIAID Information System Security Officer (ISSO).

   d) A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls, and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to NIH/DHHS for its own system's security reporting requirements.

   e) The preparation and submission, for Project Officer approval, of a RA following the guidance given in the HHS SecureOne Policy. The RA is to be maintained and updated every three years, or in advance of implementing major system modifications or enhancements.

   f) The development and maintenance of an up-to-date COOP following the guidance in the HHS SecureOne Policy. At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months.

   g) Plans, procedures and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data from the clinical and laboratory sites. This includes data integrity and security during electronic transmission or during transit from the study sites to the SDCC if non-electronic data transmission is used. All subject identifiable data is subject to the Privacy Act, Health Insurance Portability and Accountability Act (HIPAA) and DHHS regulations.

10) For a site with intermittent internet connection, provide a system for off-line data entry. Data may be transmitted at a later time when internet connection is available.

11) For a site with unreliable electrical power, implement alternate power source, back-up systems and/or contingency plans.

c. Data Quality Control System

1) The Contractor shall design and implement and maintain a quality control system for monitoring the accuracy, completeness and timeliness of the data by study sites at each stage of a study beginning with study initiation/patient enrollment and proceeding to the

generation of final data sets. The system shall have the following features and capacities and shall provide for verification of 100 per cent of study data:

a) Computerized validation and error-checking (e.g. range checks, user logics) to evaluate and improve the accuracy, timeliness and completeness of data submitted by the clinical sites.

b) Strategies to assure uniform standardized data collection and appropriate implementation of multi-center studies across participating clinical sites.

c) A computerized data query system to notify and request resolution from clinical and laboratory sites when aberrant and/or missing data are identified.

d) Annual review and revision of manuals and procedures documenting data collection, editing and validation procedures and standards.

2. **Study-Related Materials**

a. The Contractor shall prepare materials for the implementation of clinical trials and clinical studies, including Manuals of Operations (MOOs), electronic or paper Case Report Forms (CRFs), source documents, questionnaires, memory aids, subject instructions, screening and recruitment logs, order forms for clinical supplies and test articles, and test article accountability logs.

b. Draft materials will be reviewed by the Project Officer and/or relevant DMID staff, clinical sites and industry collaborators and revised as necessary to incorporate recommended modifications.

3. **Clinical Study Website(s)**

a. Within 90 calendar days after the effective date of the contract, establish, maintain and update one or more websites to share clinical research information and study materials with the Project Officer and/or relevant DMID staff and participating study sites. The Project Officer will approve those websites. This shall include the following:

1) The establishment, maintenance and updating of protocol-specific, password-protected websites to access protocol information and real-time study data.

2) The provision of access by the Project Officer and/or relevant DMID staff, study sites and industry collaborators to study-specific materials, including:

a) protocols and protocol amendments;
b) consent forms;
c) investigator brochures and/or package inserts;
d) MOOs containing instructions for clinical site staff regarding study procedures;
e) standardized forms (electronic or paper CRFs) for the collection of required data on study subjects, including eligibility, demographics (including age, gender and ethnicity), sequential clinical and laboratory outcome assessments, and acute and long-term adverse events;
f) source documents;
g) instructions for study participants;
h) tracking and dispensing logs;
i) order forms for test articles and clinical supplies;

j) logs of frequently asked questions with answers; and
k) other materials at the discretion of the Project Officer and/or relevant DMID staff.

3) Updating all website documents and materials, including new or modified versions of website materials, during the course of a clinical trial or clinical study, and providing e-mail notifications to participating study sites to alert them about the availability of new or revised materials.

4) The provision of real-time access to study data by site and total overall, including accrual, adverse event and serious adverse event listings, protocol deviations, specimen tracking and inventory, missing forms, visit schedule compliance, data queries and progress monitoring information/materials.

4. **Study Communication, Collaboration and Reporting**

a. During study implementation, the Contractor shall coordinate and collaborate with the Project Officer and/or relevant DMID staff and other DMID clinical research support services contractors to facilitate study implementation, assess study progress and evaluate processes and procedures. This shall include coordination and collaboration with: (i) the DMID Clinical Trials Management (CTM) contractor responsible for pharmacoviligence (PGV) activities, including Serious Adverse Event (SAE) reporting and safety oversight, collecting essential documents, activating study sites, clinical site monitoring and quality assurance services; and (ii) the DMID Clinical and Regulatory Affairs Support contractor responsible for the receipt, storage and distribution of test articles as well as the receipt, storage and shipment of study specimens to a central laboratory.

b. Specifically, the Contractor shall:

1) Coordinate and collaborate with the DMID Clinical Trials Management (CTM) contractor to:

a) *Study initiation*: Plan study initiation meetings with the Project Officer and/or relevant DMID staff designated by the Project Officer and the CTM contractor;
b) *Protocol-specific and site-specific randomization and data entry screens*: Open protocol-specific and site-specific randomization and data entry screens following approval from the Project Officer and/or relevant DMID staff designated by the Project Officer and receipt of a site activation letter generated by the CTM contractor;
c) *Adverse and Serious Adverse Events*: Compare and reconcile the clinical Adverse Event (AE) database with the pharmacovigilence (PGV) Serious Adverse Event (SAE) database maintained by the CTM contractor;
d) *Reporting on halting rules*: Report via e-mail to the Project Officer and/or relevant DMID staff designated by the Project Officer, CTM contractor and the Safety Oversight Structure immediately after a study halting rule is triggered;
e) *Reports for Safety Oversight Structures*: Generate and submit to the CTM contractor reports for distribution to and review by study Safety Oversight Structures as specified by the clinical protocol and the Safety Oversight Structures;
f) *Study site-specific reports*: Generate site-specific reports for the Project Officer and/or relevant DMID staff designated by the Project Officer and the CTM contractor to include accrual, demographics, line-listings of AEs and SAEs, protocol deviations, data queries, timeliness of data submission and response to queries for quality assurance purposes as appropriate;

g) *Clinical site monitoring*: Plan specific aspects of site monitoring visits and, where appropriate, identify, verify and recommend remedies to address deficiencies identified during data submission (e.g. numerous protocol deviations) or during previous site visits (e.g., selecting computerized data elements to be verified); provide data entry screens for the clinical site monitors to document their record review and provide a status update of monitoring progress for each study at each participating study site; and
h) *Randomization and test articles*: Assess compliance with randomization and appropriate administration of test articles, compare randomization to the quantity of test article shipped to each study site and the quantity of test article in stock, as verified by the clinical site monitor.

2) Coordinate and collaborate with the DMID Clinical and Regulatory Affairs Support contractor to perform the following:

a) *Specimen tracking*: Track study specimens collected at sites and timeliness of shipments to the repository maintained by the DMID Regulatory Support contractor; and
b) *Specimen inventory*: Generate specimen lists from the electronic specimen inventory and submit to the DMID Clinical and Regulatory Affairs Support contractor to select and ship specimens to specified laboratories or other destinations as appropriate.

3) Participate in the two-day annual meeting of the Vaccine and Treatment Evaluation Unit (VTEU) investigators and study coordinators to discuss on-going and proposed clinical studies.

5. **Statistical Design and Analysis**

a. The Contractor shall provide advice and assistance in the development of appropriate statistical designs and statistical analysis plans and in the preparation of interim and final analyses for clinical trials and clinical studies supported under DMID-funded clinical research programs. Concepts and protocols for DMID-supported clinical trials and clinical studies shall emanate from various sources, including clinical investigators, DMID staff and industry collaborators. Specifically, the Contractor shall work with the Project Officer and/or other relevant DMID staff, clinical investigators and industry collaborators designated by the Project Officer to perform the following:

1) Statistical Design

a) Develop and refine experimental study designs, including appropriate control/comparison groups, inclusion and exclusion criteria, sample size and power estimates, primary and secondary endpoints, randomization and stratification/blocking methods, and masking approaches.

b) Review successive versions of protocols and provide recommendations on statistical design issues.

c) Develop and refine interim and final data analysis plans.

d) Provide statistical advice concerning issues such as power, sample size, impact of interim analyses, and the inclusion of women, minorities and children in study populations.

e) Develop new applications of statistical or information science theory and present to the Project Officer and/or other relevant DMID staff and study investigators.

2) Statistical Analysis

a) *Interim analyses*: Perform interim analyses for safety, immunogenicity and/or efficacy in accordance with the approved protocol. Summarize and present interim findings to the designated Safety Oversight Structures.

b) *Final analyses*: Conduct comprehensive final statistical analyses, including descriptive as well as univariate and multivariate inferential analyses, in accordance with the approved protocol or as requested by Safety Monitoring Committees (SMCs), Data Safety Monitoring Boards (DSMBs), the Project Officer and/or relevant DMID staff, or study investigators, for use in safety monitoring and in the preparation of abstracts, journal articles and scientific presentations.

c) *Regulatory Submissions for Vaccines, Biologics, Drugs and Devices*: Prepare and present, in conjunction with the Project Officer and/or relevant DMID staff, study investigators and industry collaborators, statistical designs, statistical analysis plans and study-specific analyses for interactions with the U.S. Food and Drug Administration (FDA) in connection with pre- and post regulatory submissions. Assist the Project Officer and/or relevant DMID staff, study investigators and industry collaborators in responding to FDA inquiries regarding clinical trial design and analysis at any point during a study.

d) *Expedited analyses*: Conduct expedited analyses of data for selected high-priority studies and provide for the rapid transfer of data, data documentation and analyses to the Project Officer and/or relevant DMID staff, other Federal agencies or industry collaborators at any point during a study.

e) *Pre-Publication/Presentation Analyses*: Prior to presentation or submission for publication, review for accuracy all abstracts, manuscripts, and presentations that include data generated from clinical trials and clinical studies supported under this contract.

6. **Clinical Site Training, Assessment and Technical Assistance**

a. The Contractor shall participate in training clinical site personnel, along with DMID and other contractors, including clinical investigators, study coordinators, research nurses and data managers, with respect to procedures for study implementation in accordance with the approved protocol, MOOs, CRFs, and study participant instructions, and for the collection, management, quality control and transfer of study data to the central data management facility. Such training shall be conducted via meetings, conference calls and/or webcasts, as determined by the Project Officer. In cases where protocol-specific requirements include the conduct of pre-study site assessment or study-specific initiation activities, the Contractor shall assist and participate in planning and conducting such activities in conjunction with the Project Officer and/or the DMID CTM contractor as directed by the Project Officer. Specifically, the Contractor shall:

1) Prepare and make available to DMID staff and study and laboratory sites designated by the Project Officer an internet data entry system user's manual within 60 calendar days after the effective date of the contract.

2) Within 60 calendar days after the effective date of the contract, implement a "training data entry module" on the internet data entry system to allow study site staff to learn, practice and refresh skills in the use of the data entry system.

3) Prepare instructional materials regarding study procedures and conduct training for study site staff, including study investigators, site coordinators, research nurses, monitors and, where applicable, data managers and data entry personnel, via meetings, conference calls and webcasts. Training topics shall include: design of data collection materials; data entry; data management; data validation; audit trails; and use of the electronic specimen tracking system. Training may be provided in a variety of settings including at clinical sites or at group meetings, requiring travel of Contractor staff to domestic and international clinical sites.

4) Establish and maintain a 24 hour/7-days per week telephone help line to receive study and data management questions and requests for assistance from study sites.

5) Provide consultation and assistance to study sites in establishing or modifying SDCC computerized data entry and management systems so they may use the web-based data entry system, and in establishing quality assurance procedures.

6) Assess the capabilities of DMID-supported study sites that do not utilize SDCC computerized data entry and management systems to collect, manage and analyze data in terms of on-site technical expertise and data systems in place to collect, manage, secure, validate, and analyze data. Provide findings of such assessments to these study sites, the Project Officer and/or relevant DMID staff designated by the Project Officer within 30 calendar days of the assessment in a written report, and provide guidance, direction and follow-up to assist such clinical sites in establishing and maintaining data systems in accordance with ICH and GCP guidelines, (http://www.ich.org/cache/compo/276-254-1.html)

7. **Electronic Specimen Tracking System**

a. The Contractor shall design, implement, operate and update an electronic specimen tracking system, for use by the SDCC, study sites and laboratories, and the specimen repository maintained by the DMID Clinical and Regulatory Affairs contractor, to track study specimens in real time. The electronic specimen tracking system shall have the following features and capabilities:

1) Integration with the clinical data management system.
2) Use of bar code labels on specimen aliquots that link a unique bar code to a specific study, subject, study site and visit. Generally, study specimens are collected, processed and stored at the clinical site until they are shipped to the DMID specimen repository. The repository scans and stores the specimens until they are shipped to a central laboratory.
3) Generation of an electronic shipping manifest for receipt by the receiving facility as specimens are being scanned and prepared for shipment.
4) Provision of labels to study sites for specimen aliquots, ensuring protection of confidentiality and blinding of laboratory staff to specimen identity.
5) Provision of a real-time global inventory of all study specimens and the location of individual specimens for each specific study.

8. **Data Storage**

Serve as a data storage facility for studies conducted by DMID-supported investigators and collaborative groups, and for study sites that are scheduled to close. Transfer of data, medium, timeframe and other details shall be determined by the SDCC and the transferring study sites or investigators with Project Officer concurrence.

9. **Facilities, Equipment and Other Resources**

a. The Contractor shall provide and maintain the following facilities, equipment and other resources for the period of performance of the contract to carry out the requirements set forth in the Statement of Work:

1) A central facility for data collection, computer processing, storage, tracking and retrieval of all study data and study-related information.

2) All computers, hardware and software, computer equipment and servers.

3) Resources to ensure secure internet access.

4) Appropriate space for staff and equipment.

5) Controlled access areas for secure storage of study data and confidential study information.

6) An off-site, separate, secure and access-controlled facility for back-up copies of data.

7) Web-cast and video capability for training purposes that can be uploaded to the internet.

10. **Project Management**

a. Overall Project Management

1) Provide for the overall management, integration and coordination of all contract activities.
2) Provide an infrastructure to ensure the efficient planning, initiation, implementation and timely completion of all projects carried out under this contract and effective communications with the Project Officer and the Contracting Officer.
3) Provide for a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines.
4) Ensure the effective and efficient coordination of specified functions in collaboration with the DMID clinical research support services contractors and clinical sites identified in the Statement of Work.

b. Meetings and Teleconferences

1) *Contract Initiation Meeting*: Within 60 calendar days after the effective date of the contract, participate in a one-day Contract Initiation Meeting with the Project Officer, the Contracting Officer and other DMID personnel designated by the Project Officer, to be held at the Contractor's site. The purpose of the Contract Initiation Meeting shall be to:

a) introduce Contractor and DMID staff;
b) discuss the terms and conditions of the contract;
c) tour the Contractor facilities;
d) report on progress/accomplishments to date; and
e) establish priorities and timelines for specific activities.

2) *Weekly Protocol Status Teleconferences*: Participate in weekly teleconferences with the Project Office and/or relevant DMID staff designated by the Project Officer to discuss the status of ongoing clinical trials/studies, identify and develop approaches to resolving problems encountered in study implementation with respect to SDCC responsibilities, and review plans for the design and initiation of upcoming studies.

3) *Site Visits*: The Project Officer and the Contracting Officer may elect to perform site visits (or reverse site visits) at any time during the contract period of performance. At a minimum, one site visit shall be conducted in each year by the Project Officer and the Contract Officer (joint visit).

c. Publications and Presentations of Contract-Generated Data

1) The Contractor shall not publish, present or disseminate any information from work performed under this contract without submission of the materials to and receipt of written approval by the Project Officer.

2) The Project Officer shall have 7 calendar days from receipt of materials to review and provide comments on an abstract and 30 calendar days from receipt of materials to review and provide comments on other publications and presentations. If the Project Officer does not respond within these time frames, the Contractor may proceed with such publications or presentation.

11. **Initial and Final Transitions**

a. Initial Transition:

1) If applicable, the successor Contractor and out-going contractor shall work together to implement an orderly, secure and efficient initial transition of contract data, protocol documents and instructions and other contract-generated materials. This initial transition will follow the plan developed by the out-going contractor, providing detailed instructions on the data management and quality control system(s), as well as specific study records and datasets, including studies open for enrollment, in follow-up, and closed and in analysis.

2) The successor Contractor shall implement the initial transition plan in a manner which allows for the receipt and management of all data and study-related documents from any on-going studies effective on the first day of the contract via a web-based connection. In addition, within 90 calendar days after the effective date of the contract, the successor Contractor shall:

a) Have a website and data collection and verification systems in place for all studies. First priority shall be given to high-priority studies as determined by the Project Officer; second priority shall be given to studies open to enrollment; third priority shall be given to studies in development and nearing finalization; and last priority shall be given to closed studies and those in early development.

b) Be able to perform data mining and/or analysis on transferred datasets.

b. Final Transition

1) The Contractor shall ensure an orderly, secure and efficient transition of contract-generated data, protocol-related documents and other materials to a successor contractor or to the Government. This shall include the following:

a) Draft Final Transition Plan: Prepare and submit, for Project Officer and Contracting Officer review and approval, a draft Final Transition Plan 12 months prior to the completion date of the contract. The Draft Final Transition Plan shall provide a description of transition activities to be carried out and a timeline for the implementation and completion of all final transition activities. Contract-generated materials and data to be transitioned shall include the following:

(1) Clean, edited public use dataset and copies of all data management tools, including data documentation, data dictionaries and data entry software and editing programs to allow reading and analysis of the data for all studies managed or analyzed under the contract, including:

(a) all computer programs used for reading, cleaning, manipulating, graphing and analyzing data and programs used for generating new datasets;
(b) audit trail of all data corrections, hard copies of the original data if collected under this contract and all logs and records related to data collection, entry, editing, verification, analysis and transfer;
(c) final summaries of analyses performed during the contract period;
(d) all electronic files transferred in a format that is well-documented to a location specified by the DMID Project Officer by contract completion date. This would include transfer of the specimen inventory with documentation adequate for the new contractor to institute a new or modified specimen tracking system; and
(e) all hard copy files, including all reports submitted to DMID in an organized manner, providing clear documentation of contents, date of origin, and purpose to a location specified by the Project Officer prior to contract completion.

b) Final Transition Plan: The Final Transition Plan shall be submitted six months prior to the completion date of the contract.

c) The Contractor shall maintain full operational capability until the completion date of the contract.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS AND DELIVERABLES

Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases RFP NIH-NIAID-DMID-08-04

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract.

All reports shall be submitted in an electronic format approved by the Project Officer. Electronic files shall be sent by e-mail or on computer discs (CD) by U.S. mail or courier service.

All reports shall include a cover page containing:

- Contract title and number
- Title of report
- Protocol identifier (if applicable)
- Period of performance being reported
- Contractor's name, and address
- Date of submission

A. Technical Reports

1. Monthly Electronic Study Spreadsheet Report

a. The Monthly Electronic Study Spreadsheet Report shall include a line listing of all studies, identified by study number, in which the Contractor is actively engaged. The report shall be organized according to the following categories of clinical studies:

1) studies in development;
2) studies open and enrolling;
3) studies in follow-up; and
4) closed studies with analytic and report activities in progress.

b. Fields shall capture study number, sample size (n=), PI, NIAID Project Officer, assigned Contractor staff, clinical sites or expected number of sites, and comment fields for study status and/or action items.

c. The Report shall also identify any problems encountered for subsequent discussion with the Project Officer.

d. Other pertinent contract activities shall also be reported, including:

1) the number of reports generated for Safety Oversight Structures and/or annual Investigational New Drug (IND) submissions;
2) the number of operational web sites and web pages;
3) the number and types of training provided, including title of training, presenters, recipients, locations and methods of training;
4) a description of paper, poster, manuscript review or development activities;
5) activities related to tracking specimen inventory; and

6) ad hoc requests for services, a description of the services provided and name of the requestor.

2. **Monthly Expenditure Report**

The Monthly Expenditure Reports shall include cumulative spending for each protocol as well as a breakdown of expenditures for each protocol, including: personnel (number of hours expended for each study and cumulative overall), consultants (identify specific protocol and role), materials and supplies, equipment (specify), staff travel (identify protocol and purpose of travel), other direct costs.

3. **Semi-annual Technical Progress Report**

a. The Contractor shall submit a Semi-annual Technical Progress Report which summarizes the activities in progress and completed in the preceding six months and shall include:

1) Table of Contents;
2) Summary of work performed for each protocol;
3) Identification of issues and problems, their resolution or proposed approaches for resolution and estimated costs for resolution; and
4) Any additional information pertinent to contract performance.

b. A Semi-annual Technical Progress Report is not due when the Annual Technical Progress Report or Final Report is due.

4. **Annual Technical Progress Report**

a. The Contractor shall submit an Annual Technical Progress Report which summarizes the activities in progress and completed in the preceding 12 months and shall include:

1) Table of Contents;
2) Summary of work performed for each protocol;
3) Identification of issues and problems, their resolution or proposed approaches for resolution and estimated costs for resolution; and
4) Any additional information pertinent to contract performance.

b. An Annual Technical Progress Report shall not be not due when a Final Report is due at the end of the contract.

5. **Site Visit Reports**

The Contractor shall submit a Site Visit Report within 14 calendar days following each site visit providing the following information:

1) the date of the visit;
2) the site visited;
3) the purpose and objectives of the visit;
4) the participating staff (Contractor and site personnel);
5) the findings of the visit;
6) any issues or problems identified during the visit; and
7) any actions taken to resolve issues or problems or recommendations for follow-up.

6. **Site Assessment Reports**

The Contractor shall submit a Site Visit Report within 30 days following each site visit providing the following information:

1) the date of the visit;
2) the site visited;
3) the participating staff (Contractor and site personnel);
4) the findings of the visit;
5) any issues or problems identified during the visit; and
6) any actions taken to resolve issues or problems or recommendations for follow-up.

7. **Final Report**

a. Draft Final Report

A draft of the Final Report shall be submitted 90 calendar days prior to the completion date of the contract. The Project Officer will provide comments back to the Contractor within two weeks of receipt of the draft Final Report. The Contractor shall submit the Final Report which incorporates the Project Officer's comments on or before the completion date of the contract.

b. Final Report

The Final Report shall include final analyses of the data on sex/gender and race/ethnicity and shall describe all work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. In addition, as part of the Final Report, the Contractor shall submit a Summary of Salient Results (not to exceed 200 words) achieved during the performance of the contract.

B. **Technical Reports Delivery Schedule**

1. Satisfactory performance of the contract is defined as satisfactorily performing the statement of work and delivering the following items.

Progress Reports

Item	Type of Report	Delivery Schedule
a.	Monthly Electronic Study Spreadsheet Report	The first reporting period shall include any fractional part of the initial month. Every report is due the 30th of the month following each reporting period.
b.	Monthly Expenditure Report	The first reporting period shall include any fractional part of the initial month. Every report is due the 30th of the month following each reporting period.
c.	Semiannual Technical Progress Report	Due on/before the 30th of the month following each six-month reporting period. A Semiannual Report is not due when an Annual Technical Progress Report or Final Report is due.

d.	Annual Technical Progress Report	Due on/before the 30th of the month following each anniversary date of the contract. An Annual Report is not due when a Final Report is due.
e.	Site Visit Reports	Each site visit report shall be submitted within 14 calendar days following the completion of each site visit.
f.	Site Assessment Reports	Each site visit report shall be submitted within 30 calendar days following the completion of each site visit.
g.	Draft Final Report	Due three months prior to the completion date of the contract.
h.	Final Report	Due on/before the completion date of the contract. (To include all corrections to the Draft Final Report as recommended by the Project Officer.)

2. The above reports will be addressed and delivered to:

Recipient	**Deliverables**	**Quantity**
Project Officer National Institutes of Health NIAID, DMID Office of Clinical Research Affairs 6610 Rockledge Drive Room 6063, MSC 6603 Bethesda, MD 20892-6603	All	2 paper copies 1 electronic copy
Contracting Officer National Institutes of Health NIAID, DEA Office of Acquisitions 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	All	1 paper Original 1 electronic copy

C. **Other Deliverables**

1. Within 60 calendars days after the effective date of the contract:

   a. Prepare and make available to DMID staff and study and laboratory sites an internet data entry system user's manual. (See SOW 6.a.1.)

   b. Implement a "training data entry module" on the internet data entry system to allow study site staff to learn, practice and refresh skills in the use of the data entry system. (See SOW 6.a.2.)

2. Within 30 calendar days after the effective date of the Contract, the Contractor shall submit a Systems Security Plan (SSP). Thereafter, the SSP shall be submitted annually.

   The SSP shall provide all information required by HHS Secure One Policy and shall contain information about system interconnectivity with other networks and system infrastucture.

3. On or before the completion date of the contract, the Contractor shall provide:

    a. Clean, edited public use dataset and copies of all data management tools, including data documentation, data dictionaries and date entry software and editing programs to allow reading and analysis of the data for all studies managed or analyzed under this contract;
    b. All computer programs used for reading, cleaning, manipulating, graphing and analyzing data and programs used for generating new datasets;
    c. Audit trail of all data corrections, hard copies of the original data if collected under this contract and all logs and records related to data collection, entry, editing, verification, analysis and transfer;
    d. Final summaries of analyses performed during the contract period;
    e. All electronic files in a format that is well-documented to a location specified by the DMID Project Officer by contract completion date. This would include transfer of the specimen inventory with documentation to institute a new or modified specimen tracking system; and
    f. All hard copy files, including all reports submitted to DMID, in an organized manner, providing clear documentation of contents, date of origin, and purpose to a location specified by the Project Officer prior to contract completion.

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ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

It is strongly recommended that offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

The following additional Technical Proposal instructions reflect the requirements of the RFP and are meant to provide additional instructions as well as a uniform format for Technical Proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors should follow the instructions in Section L of the solicitation and include the information requested in this appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference material, appendices and attachments, the Technical Evaluation Criteria, and the RFP as a whole in the development of their Technical Proposal.

Offerors who propose subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the entire technical proposal package is 200 pages inclusive of all attachments and appendices.

Pages in excess of the limit will be removed and will not be read, evaluated, or considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

A. PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or copy.
B. PROJECT OBJECTIVES, NIH FORM 1688
C. TABLE OF CONTENTS
D. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested limit of 3 pages)

Provide a brief overview of the proposed SDCC, including descriptions of the following:

A. The activities to be performed by the offeror and all proposed subcontractors, including the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.

B. The key features of the proposed computer-based systems for:

- data collection,
- storage,
- tracking and retrieval;
- electronic specimen tracking; and
- quality control for monitoring the data accuracy, completeness and timeliness by study sites.

The system shall be equivalent or comparable to one of the platform/systems:

- AdvantageEDC
- Oracle
- Oracle Clinical
- Clintrial

C. The facilities and equipment to be made available by the offeror and all proposed subcontractors, including:

- the central facility for data collection, computer processing, storage, tracking and retrieval of all study data and data-related information;
- the off-site facility for back-up copies of data;
- the electronic specimen tracking system; and
- web-cast and video capabilities.

SECTION 3: TECHNICAL PLAN/APPROACH

A. Data Collection, Management and Quality Control (SOW items 1 and 8)

Describe proposed plans and procedures to establish, maintain and update one or more data collection systems and to provide for the quality control of all clinical and laboratory data, including:

1. The number and scope of data collection systems to be developed and the rationale for each. Describe in detail the interaction among and between data systems.

2. The data entry system to be used. Include the minimal requirement for data entry terminals at the study sites. Discuss plans and procedures for accommodating special circumstances.

3. The plans and procedures for data integrity and quality checks. Include timing, scope, user verification, notifications and security considerations as well as documentation and established procedures.

4. The plans and procedure for data edits. Discuss compliance with regulatory requirements.

5. The plans and procedures for handling halting rules triggers. Include timing, scope, user verification, notifications and security considerations.

6. The data storage plans. Include a description of back-up procedures, disaster recovery procedures and query abilities.

7. The plans and procedures of the reporting system. Include timing, adaptability and distribution of reports.

8. The plans for freezing and locking databases. Include timing, reversibility and quality assurance plans.

9. The plans and procedures to ensure compliance with regulatory and international guidance requirements.

10. The plans and procedures for computer-based randomization.

11. The plans and procedures to provide security against anticipated risks. Provide the AIS, SSP and COOP.

12. The plans and procedures to provide the database to regulatory agencies and industry collaborators.

13. A description of similar data systems designed, maintained and updated in support of clinical research programs.

B. Study-Related Materials and Clinical Study Websites (SOW items 2 and 3)

1. Study-Related Materials

Discuss past experience with and describe proposed plans and procedures to develop, maintain and update study-related materials. This includes:

a) The plans and procedures for generating electronic and paper CRFs. Provide examples of CRFs produced for vaccine clinical trials.

b) The table of contents for a Manual of Operations.

c) The Data Management section for a Manual of Operations.

d) Examples of previously generated source documents, questionnaires, memory aids, subject instructions, screening and recruitment logs, order forms for clinical supplies and test articles, and test article accountability logs for vaccine clinical trials.

e) The plans and procedures for reviewing, updating and distributing study-related materials to DMID, study sites, industry collaborators and regulatory bodies.

2. Clinical Study Websites

Describe proposed plans and procedures to establish, maintain and update one or more websites to share clinical research information and study materials with DMID and participating study sites. This includes:

a) The number of websites to be developed, the content and format for each website, the rationale for multiple websites and any interaction(s) among the websites.

b) The system to be used to ensure password-protected access on a protocol-specific basis.

c) Plans to provide real-time access to study data by site and total overall, including accrual, adverse and serious adverse event listings, protocol deviations, specimen tracking and inventory, missing forms, visit schedule compliance, data queries and program monitoring information and materials.

d) A description of similar websites designed, maintained and updated by the Offeror in support of clinical research programs.

C. Study Communication, Collaboration and Reporting (SOW item 4)

1. Coordination and Collaboration with the DMID Clinical Trials Management (CTM) Contractor:

a) Describe plans for collaborating with the CTM contractor to facilitate study implementation, assess study progress and evaluate processes and procedures with respect to the following activities: study initiation meetings; opening of protocol-specific and site-specific randomization and data entry screens; comparison and reconciliation of the clinical Adverse Event (AE) database with the pharmacovigilence (PGV) Serious Adverse Event (SAE) database; reporting on halting rules; Safety Oversight Structure reporting; study site-specific reporting; clinical site monitoring; and assessing compliance with randomization and appropriate administration of test articles.

b) Discuss the access that the CTM contractor will have to the database, addressing such issues as format of data presented, tools available to allow efficient monitoring of clinical trials and efforts to maintain the integrity of the data base.

2. Coordination and Collaboration with the DMID Clinical and Regulatory Affairs Support Contractor:

Describe plans for collaborating with the DMID Clinical and Regulatory Affairs Support contractor with respect to specimen tracking and inventory.

D. Statistical Design and Analysis (SOW item 5)

1. Discuss the preferred designs, including basic design, sample size, progression between cohorts and randomization schemes, for Phase 1, Phase 2 and Phase 3 vaccine clinical trials. Include the rationale for the preferred designs, their advantages over alternative approaches, and their potential risks/disadvantages. Address the issue of power and sample size in Phase 1 vaccine clinical trials.

2. Provide interim and final analysis plan templates for vaccine clinical trials.

3. Provide a final study report template.

4. Discuss experience in regulatory submissions of statistical analysis plans and interim and final study reports.

E. Clinical Site Training, Assessment and Technical Assistance (SOW item 6)

1. Clinical Site Training and Assessment:

Provide a plan for training clinical site personnel, including clinical investigators, study coordinators, research nurses and data managers, with respect to procedures for study implementation in accordance with the approved protocol, MOOs, CRFs, and study

participant instructions, and for the collection, management, quality control and transfer of study data to the central data management facility. This plan should include the following:

a) A description of the content and format of proposed training modules for the provision of:

   1) generic instructions and procedures for protocol initiation and implementation, and data collection, entry, quality control and transfer of data to the central data management facility;

   2) the design of data collection materials;

   3) data validation and audit trails; (iv) protocol-specific requirements and procedures; and

   4) the use of the electronic specimen tracking system.

b) Proposed plans to design, operate, update and staff a 24-hour/7 days per week telephone helpline to receive study and data management questions and requests for assistance from clinical sites.

c) Proposed plans and procedures for assisting in the planning and conduct of study-specific initiation meetings for clinical site personnel.

d) Proposed plans and procedures for assisting in the planning and conduct of pre-study site assessments to ensure the adequacy of site-specific equipment, procedures and training with respect to data collection, entry, validation and transfer, and proposed plans/activities to be carried out to improve or correct clinical site problems and deficiencies.

e) A description of the offeror's capabilities to conduct clinical site training via meetings, teleconferences and webcasts, including examples of recent experience in planning, designing and conducting such training activities.

2. Clinical Site Technical Assistance:

   a) Describe proposed plans and activities to be conducted to provide consultation and assistance to clinical sites in establishing or modifying SDCC computerized data entry and management systems in order to facilitate DMID-sponsored clinical research via the web-based data entry system, and in establishing quality assurance procedures.

   b) Describe proposed plans and activities to be conducted to assess the on-site capabilities of DMID-supported clinical sites that do not utilize the SDCC computerized data entry and management system to collect, manage and analyze data and the data systems in place to collect, manage, secure, validate and analyze data, and to provide guidance, direction and follow-up to assist such clinical sites in establishing and maintaining data systems in accordance with ICH and GCP guidelines. Discuss the timing and format of such assessments, the development of recommendations for necessary modifications/improvements, and the provision of technical assistance to implement modifications/improvements,

F. Electronic Specimen Tracking System (SOW item 7)

Provide a proposed plan for the design, implementation, operation and updating of an electronic specimen tracking system for use by the SDCC, clinical sites and laboratories, and the specimen repository maintained by the DMID Clinical and Regulatory Affairs contractor, to track study specimens in real time. This plan shall address the following required features/capabilities of the specimen tracking system:

1. Integration with the clinical data management system.

2. Use of bar code labels on specimen aliquots that link a unique bar code to a specific study, subject, study site and visit.

3. Generation of an electronic shipping manifest for receipt by the receiving facility as specimens are being scanned and prepared for shipment.

4. Provision of labels to study sites for specimen aliquots, ensuring protection of confidentiality and blinding of laboratory staff to specimen identity.

5. Provision of a real-time global inventory of all study specimens and the location of individual specimens for each specific study.

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL

The Technical Proposal should include all information relevant to document individual education, training, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of key scientific and technical personnel, including scientific and technical personnel of all proposed subcontractors. Limit CVs to 2-3 pages, include recent experience with projects of similar size and complexity, and provide selected references for publications relevant to the scope of the RFP.

A. Principal Investigator: Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract, including: statistical leadership for the design, development, implementation, and analysis of all phases of clinical trials for the evaluation of candidate vaccines, therapeutics and biologics for infectious diseases, as well as other types of evaluations and analyses; management of the overall operations of a central data management facility involving large and complex computer systems; and coordination and oversight of a broad range of support services for large and complex clinical research programs. The Government estimates the effort for the Principal Investigator to be approximately 75%.

B. Other Key Scientific and Technical Personnel: Describe the education, training, experience, expertise, qualifications, and percentage of effort for all proposed key scientific and technical personnel of the offeror and all proposed subcontractors. Document relevant qualifications for: statisticians, research staff, and systems analysts, programming and information technology professionals.

SECTION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES (SOW Item 10)

A. Provide a description and documentation of the availability and adequacy of facilities, equipment and other resources to be used for performance of the contract for the offeror and all proposed subcontractors, including:

1. the central facility for data collection, computer processing, storage, tracking and retrieval of all study data and study-related information, including the location(s) and features of the facility and lease or ownership information;

2. the off-site facility for back-up copies of data, including the location and features of the facility and lease or ownership information;

3. computers, hardware and software, computer equipment and servers, including a description of security systems in place ;

4. resources to ensure secure internet access;

5. space for staff and equipment;

6. controlled access areas for secure storage of study data and confidential study information; and

7. web-cast and video capability for training purposes that can be uploaded to the internet.

SECTION 6: PROJECT MANAGEMENT (SOW item 11)

A. Provide a plan for project organization, staffing, and management in relation to the implementation, conduct, monitoring and completion of contract requirements. Include a detailed description of the responsibilities and the level of effort for all proposed personnel who will be assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for all personnel. If consultants and/or subcontractors are to be used, include a plan to manage and coordinate consultant and/or subcontractor(s) efforts. Also include a chart of the proposed organizational/management structure for the project.

B. Describe project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.

C. Outline how the PI will communicate and interact with the Contracting Officer, the Project Officer and other DMID clinical research support services contractors.

SECTION 7: INITIAL TRANSITION (SOW item 12)

A. Provide a plan for the secure, orderly and efficient transition of clinical and laboratory data, study-related materials, and other contract-generated resources from the incumbent contractor. Include plans for transferring:

1. studies in development;
2. studies currently enrolling; and
3. studies for which enrollment has been completed.

B. Include all data elements, such as locked and frozen studies. In particular, address the following:

1. detailed plans for database transition including elements that need to be transitioned from the incumbent for a timely transition;

2. timelines and detailed plans to ensure a seamless transition of currently enrolling studies; and

3. plans to produce final study reports and other required regulatory reports for all studies in transition.

SECTION 8 - ALL OTHER DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION NOT SPECIFICALLY ADDRESSED ABOVE

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ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS and UNIFORM BUDGET ASSUMPTIONS

In addition to the format requirements for the business proposal that are contained in Section L of the solicitation, the information provided in this appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as appendices and attachments, and the Technical Evaluation Criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL

SECTION 1 – PROPOSAL COVERSHEET –
Form NIH-2043 - PROPOSAL SUMMARY AND DATA RECORD

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

SECTION 3 – UNIFORM BUDGET ASSUMPTIONS

1. Technical Cost Assumptions

a.		Ongoing Activities at Contract Award (assume responsibility for)	Assumptions
	1)	*Clinical Trials*	**Assume**: • 15 Phase 1 clinical trials in development • 40 active Phase 1 clinical trials • 20 completed Phase 1 studies for which final reports are pending • 50 completed Phase 1 trials for which data are archived

	2)	*Clinical Specimen and Database Records*	**At the time of award, assume that**: • 400,000 specimens are stored in the repository inventory • 275,000 records are stored in the database for 50,000 subjects.
	3)	*Training Webcasts*	**Assume that webcasts will be held for training purposes as follows:** • 35 webcasts/year dedicated to electronic data entry; • 35 webcasts/year dedicated to the electronic specimen tracking system; and • 12 webcasts per year for site monitors on the electronic data system.
	4)	*Study Websites*	**Assume**: 25 active clinical trial-specific websites involving 7,000 web pages at the time of award.
	5)	*Study Reports*	**Assume:** • all clinical trials will be conducted under an IND • 40 Safety Oversight Structures will require blinded safety/efficacy reports at various frequencies each year.
b.		New Clinical Trials	Assumptions
	1)	*Number*	**Assume**: • 20 new protocols will enter development <u>each</u> year of the contract period of performance • There may be as many as 70+ studies in development, in accrual, in follow-up or analysis at any point in time
	2)	*Phase*	**Assume**: • 19 of the new clinical trials per year will be Phase 1 or Phase 2 clinical trials • 1 will be a Phase 3 clinical trial
	3)	*Candidate vaccines/therapeutics and study participants*	**Assume**: • 15 of the new clinical trials per year will be vaccine trials in healthy subjects, although some of these trials may include special populations such as the elderly, i.e. greater than 65 years, pediatric populations and pregnant women • 5 of the new clinical trials per year will be treatment trials of vaccines, drugs or other biologics in subjects who are ill with the disease under study, e.g. Hepatitis C, tuberculosis, malaria

	4)	*Duration*	**Assume**: • the duration of 10 of the new clinical trials per year will be 1 year or less • 8 of the trials will be 18 months • 2 trials will be 3 years in duration
	5)	*Clinical sites*	**Assume**: • 15 of the new clinical trials per year will be multi-center (at 7 sites) • 5 of the new clinical trials will be performed at a single clinical site.
	6)	*Scope of SDCC support*	**Assume for all new clinical trials the Contractor will be responsible for**: • study design; • development of study-related materials; • data management, data quality assurance and data analysis; • the preparation of reports and other materials, including interim and final analyses, for Safety Oversight Structures; • the generation of tables for annual IND reports; • the design and maintenance of one dedicated website for each new clinical trial, each containing 100 web pages; and • a total of 5,000 users requiring access to various websites at any time.
	7)	*Study initiations*	**Assume**: • study initiations for 20 new clinical trials per year, • 13 will be conducted via teleconference or webcast, • 5 will require visits to domestic clinical sites, and • 2 will require visits to foreign clinical sites.
	8)	*Clinical specimens*	**Assume that each of the new clinical trials will require**: • 5 specimens per subject, • each divided into10 aliquots (total 50 aliquots per subject per trial) • to be collected, bar coded and tracked via an electronic tracking system.
	9)	*Data collection and management procedures*	**Assume**: • web-based data entry will be provided for all but 1 or 2 of the new clinical trials per year • these trials will require other data collection and management procedures.

	10)	*Site assessments*	**Assume**: • 7 site assessments per year for new clinical trials (3 site assessments for domestic clinical sites and 4 site assessments for foreign clinical sites
	11)	*Site visits*	**Assume:** • 5 site visits to domestic clinical sites will be conducted in each year of the contract to address special issues.

2. Meetings and Travel

	Activity to be performed	Assumptions
a.	*Contract Initiation Meeting*	**Assume:** • 1 meeting in Bethesda, Maryland within 60 calendar days after effective date of contract; 2-night stay • attendance by all of the Contractor's key personnel
b.	*Site Assessments*	**Assume**: • 7 site assessments per year • conducted by 2 individuals • 3 days for 3 domestic clinical sites • over 5 days for 4 foreign clinical sites
c.	*Study Initiations*	**For each year of the contract, assume travel for:** • 1 person for study initiation visits to 5 domestic clinical sites • travel for 1 person for study initiation visits to 2 foreign clinical sites. • all study initiations can be completed in 1 day.
d.	*Study Site Visits*	**Assume**: • 5 study site visits per year • each 2 days in duration • requiring 2 staff
e.	*VTEU or other network/group meetings*	**Assume**: • 5 meetings per year -- 3 days each ▪ 2 meetings will be held in Bethesda, MD, with 6 Contractor staff participating • 3 of these meetings will be held elsewhere in the continental U.S. with 4 Contractor staff participating

DMID-FUNDED CLINICAL RESEARCH SUPPORT SERVICES CONTRACTS

Statistical and Data Coordinating Center for Clinical Research in Infectious Diseases

The original project began in 1991 with the competitive award of a 5-year contract to Technical Resources, Incorporated, contract N01-AI-15131, that established a Data Center to organize multi-center clinical trials and to coordinate and manage the flow of data between a limited number of DMID clinical research contractors, DMID staff and manufacturers of test products. In 1996, the contract was awarded to the The EMMES Corporation, contract N01-AI-65313, to continue the support of multi-center clinical trials and to incorporate a strong statistical design and analysis component for additional DMID clinical research contractors and for a broader range of clinical studies. The contract was re-competed and awarded to The EMMES Corporation for a 7-year period beginning in July, 2001, contract N01-AI-15448. Following the tragic events of September 11, 2001, the contract was expanded in September 2002 to provide support for DMID-funded clinical research on potential agents of bioterrorism.

DMID Clinical Trials Management and Support Contract

PPD Development, LP, located in Wilmington, NC, was awarded the DMID Clinical Trials Management (CTM) contract for the period September 30, 2003 through September 29, 2008, contract N01-AI-30068. PPD provides a central resource to the DMID and its extramural investigators to support and coordinate many clinical trial-related activities including: pharmacovigilence, safety oversight via Safety Monitoring Committees and Data Safety Monitoring Boards; collection of regulatory and essential documents; and clinical site monitoring. The CTM contractor also maintains a website with research resources and standardized procedures. Specific responsibilities include:

1. Clinical site assessment, evaluation of clinical sites for clinical research feasibility and capacity;
2. Clinical site preparation and clinical trials operations and assistance; study document preparation and review;
3. Clinical site assistance for establishment of internal quality control and quality assurance;
4. Training in Good Clinical Practices;
5. External clinical site monitoring to include site initiation, interim and close-out visitis and quality audit visits;
6. Centralized pharnacovigilence and safety monitoring; and
7. Information and document management through web-based systems.

DMID Clinical and Regulatory Affairs Support Contract

Fisher BioServices Corporation, located in Rockville, Maryland, was awarded the DMID regulatory support contract for the period August 1, 2001 through July 31, 2008, contract N01-AI-05413. Fisher BioServices provides regulatory support services including:

1. Preparation and maintenance of Investigational New Drug (IND) applications;
2. Consulting and audit for manufacturers of NIAID/DMID products;
3. Management and operation of a clinical agent repository for distribution and tracking of IND products; and
4. Management and operation of a clinical specimen repository for short-term storage.

DMID CLINICAL RESEARCH CONTRACTS

Vaccine and Treatment Evaluation Units (VTEUs)

Established in 1962, the NIAID Vaccine and Treatment Evaluation Units (VTEUs) are composed of university research hospitals across the United States that conduct Phase 1, 2, 3 and 4 clinical trials to evaluate candidate vaccines and therapeutics for a broad range of infectious diseases, including potential agents of bioterrorism. The VTEU program currently consists of the seven contracts listed below. Recompetition of the VTEU contracts is underway and awards are anticipated in early FY 2008 (see Request for Proposals at http://fs1.fbo.gov/EPSData/HHS/Synopses/3465/NIH-NIAID-DMID-08-03/NIAID-DMID-08-03RFP.pdf)

Current VTEU Contractors

Baylor College of Medicine	N01-AI-25465
Cincinnati Children'sHospital Medical Center	N01-AI-25459
Harbor UCLA Medical Center	N01-AI-25463
Saint Louis University	N01-AI-25464
University of Maryland, Baltimore	N01-AI-25461
University of Rochester	N01-AI-25460
Vanderbilt University	N01-AI-25462

DMID Viral and Respiratory Pathogen Research Unit (VRPRU)

The VRPRU (Contract No. N01-AI-30039) was awarded to Baylor College of Medicine in 2003. This center conducts preclinical and clinical studies including Phase 1 and Phase 2 clinical trials of vaccines, therapeutics, diagnostics, other biologics and drugs as preventive and therapeutic measures against viral respiratory pathogens. The focus is on translational and clinical research. Current studies include one Phase 1 clinical trial and one Phase 2 clinical trial, involving approximately 100 and 400 subjects, respectively.

DMID Bacterial and Respiratory Pathogen Research Units (BRPRU)

The BRPRU (Contract No. N01-AI-30040) was awarded to the University of Iowa in 2003 to conduct preclinical and clinical studies including Phase 1 and Phase 2 clinical trials of vaccines, therapeutics, diagnostics, other biologics and drugs as preventive and therapeutic measures against bacterial respiratory pathogens. The focus is on translational and clinical research. Current studies include one Phase 1 clinical trial involving approximately 60 subjects.

Malaria Vaccines: Clinical Research and Trial Sites in Endemic Areas

This contract (Contract No. N01-AI-40016) was awarded to Noguchi Memorial Institute for Medical Research on June 1, 2004. Two subcontracts are currently in place in Ghana and Burkina Faso, respectively, with a third subcontract at another site in Ghana expected to be in place by 2007. Each of the subcontracts calls for three Phase 1 or two Phase 2 malaria vaccine trials or some combination of Phase 1 and 2 trials with up to 1,500 subjects enrolled each year. A Phase 3 trial (n = ~ 6000 children) may open by 2009.